

Serial No. 09/996,184
Reply & Amendment After Final
Page 5 of 6

REMARKS

Applicant kindly thanks the examiner for the telephonic interview held on December 1, 2005. During the interview the new rejections under §112 were discussed and how support for the disputed claim terms could be found in the application. Applicant hereby submits the instant response addressing the points discussed during the interview in details.

Amendment to the claim:

Claim 11 is amended to recite "a therapeutic substance". By this amendment, applicant wishes to correct the use of terms in a consistent, coherent and clear manner within the claim set. By this amendment, Applicant does not waive any scope from the claims from which claim 11 depends directly or indirectly. Support for this amendment may be found in the specification at page 10 line 18.

Claim rejections under 35 USC §112

1. Claims 8 and 10 are rejected under 35 USC §112, first paragraph as allegedly failing to comply with the written description requirement. Applicant respectfully submit that there is adequate literal support for these claims.

Specifically, claims 8 and 10 recite a pharmaceutical composition (or method of forming a composition) that further comprises a bioactive compound, a therapeutic substance or cells. At the time of submission of the amendment, Applicant pointed to literal support in the application for these terms as follows: at page 3, line 4-5 (for bioactive compound); page 3, line 25 (for cells); and page 10 line 18 (for therapeutic substance). Applicant now wishes to point out further support in the specification for such terms: page 11, line 14-15 (wherein the polymeric composition is used as a barrier "to locally deliver therapeutic materials, including polymeric therapeutics"), at page 12, lines 5-6 (referring to uses of the compositions as "Any application may further include medications, drugs, excipients or other active or cosmetically-effective ingredients).

Therefore, applicant kindly requests that this rejection be withdrawn.

2. Claims 8 and 10 are rejected under 37 CFR §112, second paragraph as allegedly being indefinite. The examiner particularly questions the difference in the

Serial No. 09/996,184
Reply & Amendment After Final
Page 6 of 6

terms bioactive substance and therapeutic substance. Applicant respectfully submits that these terms are clear and definite as being term well understood in the art.

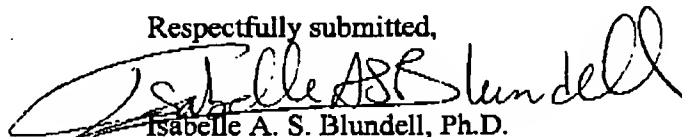
Patentability assessment under §112, second paragraph require the scope of the claims be clear so the public is informed of the boundaries of what constitutes infringement of the patent and has a clear measure of what applicant regards as the invention. See MPEP §2173. A bioactive agent, substance or compound is generally understood as an agent, substance or compound that has an effect on a biological system or any of its components (irrespective of the initial condition, e.g. healthy or distressed, of that system or of the qualitative appreciation of the effect, beneficial or detrimental, on that system). A therapeutic agent, substance or compound is a generally understood as an agent, substance or compound that when administered to a patient exhibiting a disease or condition has an effect that limits, ameliorates or even eliminates some or all of the clinical symptoms of the disease or condition in the patient.

Thus, applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

Applicant believes that all issues raised in the Office Action have been addressed in this submission and kindly requests favorable reconsideration of the instant application.

Respectfully submitted,



Isabelle A. S. Blundell, Ph.D.

Reg. No. 43,321

Attorney for Applicant

Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142
Tel. 617-768-6698
Fax. 617-252-7553
Fax. 617-768-9558 (direct)
e-mail: isabelle.Blundell@genzyme.com